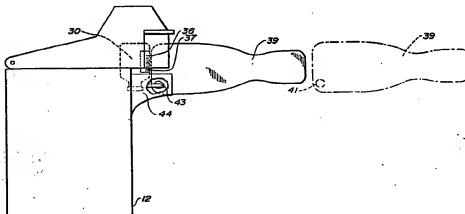




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: INFUSION PUMP SECURITY SYSTEM



## (57) Abstract

A drug identification and security system usable in conjunction with an electronic drug delivery apparatus (12, 12c) having at least one drug channel therein, the system providing a first interlock mechanism (46, 50) between a locking member (50) of the apparatus and the drug delivery apparatus to disengage the drug delivery apparatus and prevent removal of a drug container/cassette assembly when the locking member is in a locked position. A second interlock mechanism (41, 43) is interposed between a bar code reading device (39) usable with the drug delivery apparatus and an interlock switch (43) provided on the drug delivery apparatus, the interlock switch assuring the placement of a drug container in a drug channel of the drug delivery apparatus at a designated position for the drug container within the drug channel, to enable the drug delivery apparatus to deliver the drug in the container through the apparatus to the patient receiving a drug dosage in a controlled amount and at a controlled delivery rate.

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## INFUSION PUMP SECURITY SYSTEM

Field Of The Invention

5 The present invention relates to security systems generally and in particular to a drug channel identification and security system useful in a drug delivery apparatus to prevent the dispensing of drugs when the apparatus is locked and further to assure that the drug vial from which the drug is dispensed is disposed in a proper and machine readable position within the drug delivery apparatus.

10 Background Of The Invention

It is known to provide a locking enclosure for a drug delivery device such as a programmable infusion pump to permit the pump to be used as a patient-controlled analgesia (PCA) device. For example, depicted in U.S. Pat. No. 4,627,839 entitled "Patient Controlled Analgesia Conversion", is a pump which infuses a drug into the patient at a 15 dosage set by the doctor but at a rate controlled by the patient. To prevent the patient from accessing the pump to obtain more drug than prescribed, safety interlocks are provided to disable the keyboard once dosage requirements have been set and the pump is operative. However, 20 under certain circumstances it might be necessary to disable the mechanism itself, as in a drug delivery situation where the physician needs to be present during the time of drug delivery and needs to

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prevent the delivery of drugs in his absence. An accommodation as described above is not available in the aforementioned device.

Another form of locking member associated with a patient controlled analgesia device is shown in U.S. Pat. 5,009,641 entitled "Patient-Controlled Analgesia Security Attachment For A Medication Infusion System". The subject patent discloses both a compartment for securely storing a medication supply and means for preventing either a cassette associated therewith or a fluid line between a storage compartment and a cassette from being removed or tampered with. However, such an attachment offers no advantage to the programming of multiple infusion devices and further does not permit the disablement of such devices subsequent to programming and prior to use so as to prevent unauthorized activation of the device when the physician programming the device is not present.

While it may be possible to provide within a single drug delivery apparatus a bar code reader fixedly mounted on the device, such as shown in U.S. Pat. 4,978,335 entitled "Infusion Pump Of Bar Code Input To Computer", such a scheme is not suitable for all drug delivery applications. For example, a hand-held reader may be preferable to a built-in reader for certain applications. In such applications it would be desirable to know that the vial being read is properly installed inside the device. Further, such consideration would also apply to a multi-channel drug delivery apparatus using but a single hand-held bar code reader.

Accordingly, in a drug delivery apparatus which uses a single bar code reader, it may be necessary to provide a bar code reader which is hand-held and moveable to scan the drug channel of the apparatus and further to provide the apparatus with interlock means to assure that a drug vial is properly positioned within its respective drug delivery channel of the drug delivery apparatus and further means to assure that the bar

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code on the drug vial is so positioned within its respective drug delivery channel in the drug delivery apparatus so as to enable such a free standing and moveable scanning device to read the drug vial disposed in a drug delivery channel, as well as each drug vial placed in its respective drug delivery channel and associate the respective drug with that channel in an apparatus which incorporates but a single scanning device. Moreover, in such a proposed apparatus it is clearly necessary that the apparatus prevent the scanner from reading the bar code of a drug vial not installed in the apparatus or a drug vial not properly positioned for reading within the drug delivery apparatus.

#### SUMMARY OF THE INVENTION

In accordance with the present invention, a multi-channel drug delivery apparatus includes a drug identification and security system to insure proper placement of a drug vial within a discrete channel of the apparatus, and further to provide that a simple turn of a key will electronically disengage the system to prevent its operation in the absence of the physician attending the apparatus, as well as to prevent the removal of the drug vial.

In particular, the proposed drug identification and security system provides multiple interlocks to first insure that a drug vial installed in a preferred embodiment of the drug delivery apparatus is properly installed within a drug delivery channel of the apparatus for reading by a scanner device. A second interlock maintains the system in a closed configuration once the drug vial has been installed in the system and further electronically inactivates the system to insure that the drug contained in the vial installed therein cannot be dispensed in the absence of the attending physician.

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In accordance with the present invention, a drug identification and security system is usable in conjunction with an electronic drug delivery apparatus, the drug delivery apparatus comprising a multi-channel device wherein each drug delivery channel includes a pump mechanism, a pump cassette installed in the mechanism, a drug vial connected to the cassette via a vial adapter, and an apparatus enclosure enclosing each drug delivery channel of the device. The drug identification and security system includes a locking member in engagement with the apparatus enclosure and movable between separable lock and unlock positions. A first interlock mechanism comprises a position sensor interposed between the locking member and the drug delivery apparatus to electronically disengage said apparatus via a logic recognition circuit when the locking member is in the lock position.

Provided in association therewith is a drug identification system which includes a scanning device for reading identifying indicia, such as a bar code, provided on the drug vial. A second interlock mechanism is interposed between the scanning device and the apparatus enclosure to assure the placement of the drug vial in the apparatus enclosure at a designated position within such enclosure, to enable the drug delivery apparatus to deliver the drug in the vial through the apparatus to a patient receiving a drug dosage in a controlled amount and at a controlled delivery rate.

The proposed drug identification and security system offers multiple levels of protection to the user of the automated electronic drug delivery apparatus used in conjunction with the present invention. First the proposed drug identification interlock assures that the drug vial is placed within the apparatus before use and that the system is identifying the drug vial placed in the apparatus and not a drug vial disposed remotely from the apparatus. In a multi-channel drug delivery

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apparatus the drug identification system can read drug vials disposed in respective drug channels to identify the drug contained in the drug vial installed in a respective drug channel and enable the user to program a drug channel once its drug vial has been installed therein and identified by an appropriate scanning device.

Moreover, once a drug vial has been installed in its respective drug delivery channel and the channel has been programmed per the requirements of the attending physician, the drug identification and security system provides additional security to the attending physician by first locking the drug vial within the drug delivery apparatus, and second, electronically disabling that drug delivery apparatus in the absence of the attending physician.

Further objects and advantages of the present invention will become apparent upon a reading of the detailed description of the preferred embodiment as set forth below, particularly when such detailed description is considered in conjunction with the accompanying drawings briefly described below.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a top right perspective view of a multi-channel electronic drug delivery apparatus which employs the drug identification and security system of the present invention;

Figure 2 is a top right perspective view of the right-hand drug channel of Figure 1, with a protective hood enclosure open, to expose the drug vial therein;

Figure 3 is a front elevation of the drug channel of Figure 2, having a drug vial disposed therein;

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Figure 4 is a side elevation of the drug channel of Figure 2, showing the alignment of the drug channel with a bar code scanner;

Figure 5 is a perspective view of the bar code scanner of Figure 5;

Figure 6 is a sectional view taken generally along the lines 6-6 of Figure 1 with portions thereof removed for clarity; and

Figure 7 is a sectional view taken along the lines 7-7 of Figure 1 to display a portion of the drug identification and security system of the present invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

10 Shown in Figure 1 is a multi-channel electronic drug delivery apparatus 10. Such apparatus includes three substantially equal drug delivery channels 12a, 12b, and 12c. The system also includes a fluid delivery channel 14 adjacent the drug delivery channels 12. Drug delivery parameters are displayed on a touch screen 16. Drug delivery  
15 parameters are entered via the touch screen 16 and fluid parameters are entered via a key pad 18. A base enclosure 20 of the electronic drug delivery apparatus 10 encloses a host computer (not shown) for driving the apparatus 10. Key lock 22 is disposed on one side of the enclosure 12 and engages a security system 24 (Figure 6 and 7) discussed in  
20 detail below.

The right hand drug delivery channel 12 is in the perspective view of Figure 1. It is proposed to discuss only a single drug delivery channel 12 in detail since the drug delivery channels 12a, 12b, and 12c are identical.

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Referring now to Figures 2 and 3, it should be noted that the drug delivery channel 12 includes a drug delivery system similar to that described in U.S. Pat. No. 4,842,584 entitled Disposable Fluid Infusion Pumping Chamber Cassette and Drive Mechanism thereof, issued June 27, 1989, to the assignee of the subject application. To enable the reader to fully understand the structure of the drug infusion pump associated with the drug delivery channel of the present invention, such U.S. Patent is herein incorporated by reference. As best seen in Figure 2 and 3, the drug delivery channel 12 includes an enclosure member 22 including a pivotable lower door 27 operable in conjunction with a pivotable hood 28. As best seen in Figures 6 and 7, the lower door 27 pivots around pivot point 29 to permit a drug vial 30 to be inserted into the drug channel 12.

When the door 27 pivots to a closed position as shown in Figure 3, the drug vial 30 is disposed in position therein and a vial adapter 31, which engages a cassette 32 of a cassette assembly 36, penetrates the stopper 33 of the drug vial. The upper enclosure or hood 28 overlies the drug vial 30 when the door 27 is closed. When the hood 28 is closed, an open drug identification window 36 is disposed at a forward end of the door 28 to provide scanner access to the drug vial 30 and identifying indicia 37 provided on the drug vial in the form of a bar code.

As seen in Figures 4 and 5, the bar code 37 provided on the drug vial 30 is read by a bar code scanner 39 in which an active reading area 40 is provided at a forward end of the bar code scanner. An essential element of the present invention is a safety interlock 41 including a magnet 42 provided at a forward end of the scanner 39. When the scanner 39 is driven to a position within the drug identification window 36 sufficient to enable the scanner to read the bar code 37 provided on the drug vial 30, magnet 42 on the scanner latches a reed

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switch 43 mounted on a fixed arm 44 of the drug channel 12. It should here be noted that the magnet/combo reed switch of the preferred embodiment is just one of several means usable to sense the presence of the barcode reader.

5 Clearly it can be observed that drug channel 12 is so configured that drug identification cannot be validated until the magnet 41 is in alignment with the reed switch 43. The system will not display drug type for user confirmation until both the drug channel 12 and the drug is identified by the system. Thus, the drug identification system of  
10 the present invention will not permit a reading to be displayed on the touch screen 16 of the drug delivery channel 12 which is taken from a drug vial 30 not properly positioned in the drug delivery channel.

In Figures 6 and 7, a secondary interlock 45 associated with the drug delivery channel 12 is shown. The interlock 45 includes a longitudinal  
15 lever 46 interconnecting the lower door 27 and the upper hood 28. The lever 46 is connected to the lower door 27 at pivot point 47 and to the upper hood at a pivot point 49, with the upper hood moving about a second pivot point 50. Associated with the lever 46 is a locking bale 50 which engages the lever 46 at a tab 51 which is inserted into latch  
20 portion 53 of the lever 46.

In the preferred embodiment of the present invention, the locking bale 50 extends across all three channels of the apparatus 10, is engaged by the key lock 22 and pivots about the pivot point 53 best seen in Figure 7. When the locking bale 50 engages the lever 46, a position sensor  
25 such as a micro switch 55 is normally open to electronically disengage the multi-channel drug delivery apparatus 10. The position sensor 55 is part of a known logic recognition circuit (not shown) able to notify the host computer when the bale 50 is engaged. When the bale 50 is disengaged, it rests against an engagement member 56 of the micro-

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switch 55 to place the micro-switch in a closed position in which the drug channel 12 is activated.

Thus, a user can install a drug vial 30 in each respective drug delivery channel 12, program each channel 12 of the drug delivery apparatus 10 and lock up the apparatus through the key lock 22 which causes the bale 50 to engage the levers 46 to lock the door 27 and the hood 28 closed and also to electronically disengage the apparatus through the micro switch 55 which is normally open when the bale engages the levers 46.

When the bale 50 is released, the bale engages the micro switch 55 to a closed position which activates the drug delivery apparatus 10 to enable the attending physician to begin the infusion of the patient through one or more programmed drug delivery channels 12 of the apparatus 10. Note that the drug channel 12 is not automatically locked when a hood 28 is open and the bale is turned to a lock position. The attending physician can turn the bale 50 to a lock position then complete his installation of a drug vial 30 in an open drug delivery channel. Even when the bale 50 is in the lock position, as long as at least one vial hood 28 is in the open position, all hoods 25 can be opened. Locking does not occur until all three hoods 28 are closed at the same time. Note also that the normally open/normally closed dichotomy for the recognition circuit is the preferred configuration for the preferred embodiment and the alternative configuration is possible.

Note also that there is no interconnection between scanner interlock 41 and hood interlock 45. The attending physician may simply lock each drug vial 30 in its respective drug delivery channel 12 and scan each drug vial to program the apparatus 10 just prior to infusing the patient.

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Thus, the present drug identification and security system provides multiple safeguards for both the patient and the attending physician to ensure that the drug vial is properly installed in the device and to insure that the device can be easily electronically disengaged by the attending physician when he moves away from the apparatus. A further desirable feature of the present invention is that the drug vial is locked in the drug delivery apparatus 10 when the apparatus is disengaged, to prevent removal of the drug vial from the system when the attending physician is not present.

10 Having described the preferred embodiment of the invention, it is believed that the specific description set forth herein should not be limiting, but rather that the present invention shall be limited by the claims appended hereto.

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We claim:

1. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus, said apparatus comprising at least one pump mechanism having a pump cassette therein, a drug container, a container adapter of the cassette to connect container and cassette, and an apparatus enclosure enclosing said pump mechanism, and
- 5 said security system including:

a locking member in engagement with the apparatus enclosure and movable between separable lock and unlock positions;

a first interlock mechanism interposed between the locking  
10 member and the drug delivery apparatus to electronically disengage said apparatus and to prevent removal of the drug container and cassette assembly when the locking member is in the lock position;

a reading device for reading identifying indicia provided  
15 on the drug container; and

a second interlock mechanism interposed between the reading device and the apparatus enclosure to assure the placement of the drug container in the apparatus enclosure at a designated position within said enclosure, to enable the drug delivery  
20 apparatus to deliver the drug in the container through the apparatus to a patient receiving a drug dosage in a controlled amount and at a controlled delivery rate.

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2. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 1 wherein the apparatus enclosure includes front upper and lower doors opening to provide installation of a cassette assembly therein  
5 including a drug container, a pivotable connecting lever between the upper and lower doors, a latching portion provided in the connecting lever, and a pivotable locking bale, movable between an unlock position, disengaged from the latching portion of the connecting lever and an engaged lock position in which the bale engages the latching  
10 portion of the connecting lever, and a key lock associated with the pivotable bale to move said bale between said lock and unlock positions.

3. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 2, when the upper door of the apparatus enclosure comprises an enclosing hood for the drug container, said hood having disposed at a forward portion  
5 thereof an open drug identification window.

4. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 3 wherein the first interlock mechanism includes a position sensor electronically interposed within the drug delivery apparatus to  
5 electronically disengage said apparatus when the locking bale is disengaged from the position sensor in a lock position of the bale.

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5. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 1 wherein the second interlock mechanism includes a magnet disposed in the scanning device and a reed switch fixedly mounted in the apparatus enclosure, the activating of the reed switch and reading the identifying indicia provided on the drug container enables the system to display the drug information on the screen and access said drug channel.

6. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 5 wherein the scanning device is a bar code reader and the identifying indicia provided on the drug container is a specific bar code identifier for the drug within the container.

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7. A drug identification and security system usable in conjunction with an drug delivery apparatus, said apparatus comprising a plurality of drug delivery channels, each of which comprises a pump mechanism having a pump cassette therein, a drug container, a container adapter  
5 of the cassette to connect container and cassette, and a respective apparatus enclosure enclosing each drug delivery channel of the apparatus, said security system including:

a locking member in engagement with each drug channel enclosure of the apparatus and movable between separable lock and  
10 unlock positions;

a first interlock mechanism interposed between the locking member and each drug delivery channel of the drug delivery apparatus to electronically disengage said apparatus and prevent removal of an assembly comprising a drug container and its  
15 associated cassette when the locking member is in the lock position;

a reading device provided on each drug channel for reading identifying indicia provided on each drug container;

a second interlock mechanism interposed between the  
20 scanning device and the apparatus enclosure of each drug channel to insure the placement of the drug container in the appropriate drug channel and a designated position within said drug channel, to enable the drug delivery apparatus to deliver the drug in the container through the apparatus to a patient receiving a drug  
25 dosage in a controlled amount and at a controlled delivery rate.

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8. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 7 wherein the apparatus enclosure includes front upper and lower doors opening to provide installation of a drug container/cassette assembly  
5 therein, a pivotable connecting lever between the upper and lower doors, a latching portion provided in the connecting lever, and a pivotable locking bale, movable between an unlock position, disengaged from the latching portion of the connecting lever and an engaged lock position in which the bale engages the latching portion of the  
10 connecting lever, and a key lock associated with the pivotable bale to move said bale between said lock and unlock positions.

9. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 8, when the upper door of the apparatus enclosure comprises an enclosing hood for the drug vial, said hood having disposed at a forward portion  
5 thereof an open drug identification window.

10. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 9 wherein the first interlock mechanism includes a position sensor electronically interposed within the drug delivery apparatus to  
10 electronically disengage said apparatus when the locking bale is disengaged from the position sensor in a lock position of the bale.

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11. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 7 wherein the second interlock mechanism includes a magnet disposed in the scanning device and a reed switch fixedly mounted in the apparatus enclosure, the activating of the reed switch and the reading of the identifying indicia provided on the drug container by the reading device enabling the system to display the drug information on a touch screen and enabling the user to access that channel.

12. A drug identification and security system usable in conjunction with an electronic drug delivery apparatus as claimed in claim 11 wherein the scanning device is a bar code reader and the identifying indicia provided on the drug container is a specific bar code identifier for the drug within the container.

13. A drug identification system usable in conjunction with an electronic delivery apparatus, said apparatus comprising at least one pump mechanism having a pump cassette assembly therein, a drug container connected to the cassette assembly, an apparatus enclosure enclosing said pump mechanism, said drug identification system including a bar code reading device for reading and identifying bar code provided on the drug container;

and an interlock mechanism interposed between the reading device and the apparatus enclosure including an activating magnet on the bar code reading device and an active switch fixedly mounted on the apparatus enclosure, said switch to be activated by the proximity of the magnet on the bar code reading device to assure the placement of the drug container in the apparatus enclosure at a designated position with said enclosure, to enable the drug delivery apparatus to deliver the drug in the container through the apparatus to a patient receiving a drug dosage in a controlled amount and at a controlled drug delivery rate.

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14. A security system usable in conjunction with an electronic drug delivery apparatus, said apparatus comprising at least one pump mechanism having a pump cassette assembly therein, a drug container connected to the cassette assembly and an apparatus enclosure enclosing
- 5 said pump mechanism, said security system including:

upper and lower doors of the apparatus enclosure interconnected by a connecting lever to open said upper and lower doors to permit installation and removal of a drug container within the pump mechanism disposed in the enclosure, a latching

10 portion provided on the connecting lever, a locking bale provided on the apparatus enclosure for engagement with the connecting lever and movable between separable lock and unlock positions with respect to the connecting lever, and

a normally open position sensor which is electronically

15 connected to the pump mechanism which electronically disengages the drug delivery apparatus when the locking bale engages the latching portion of the connecting lever in a locked position therefor.

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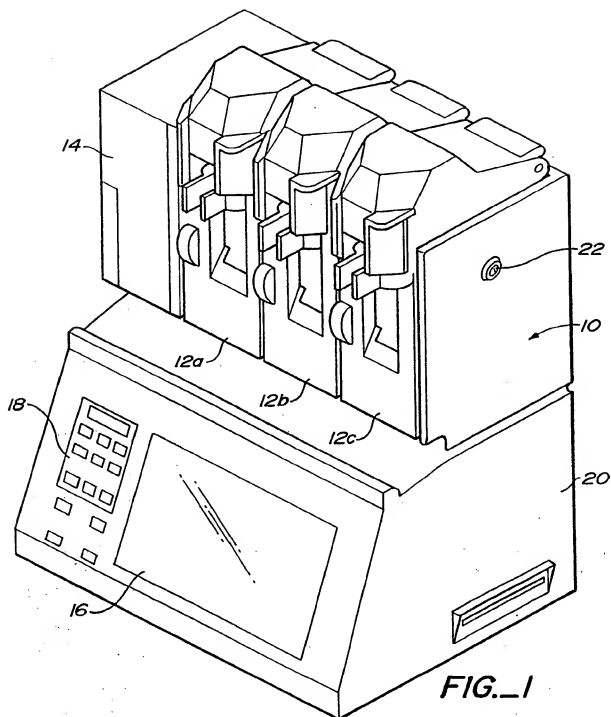


FIG. 1

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FIG.\_2

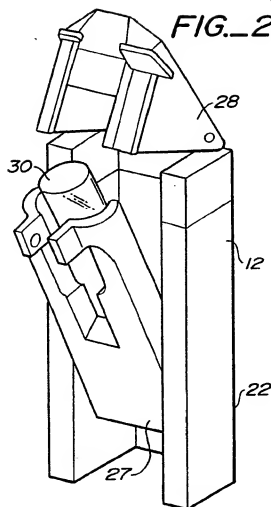
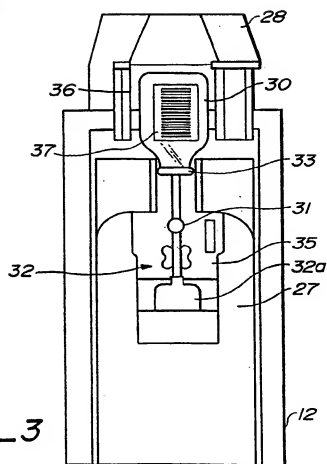
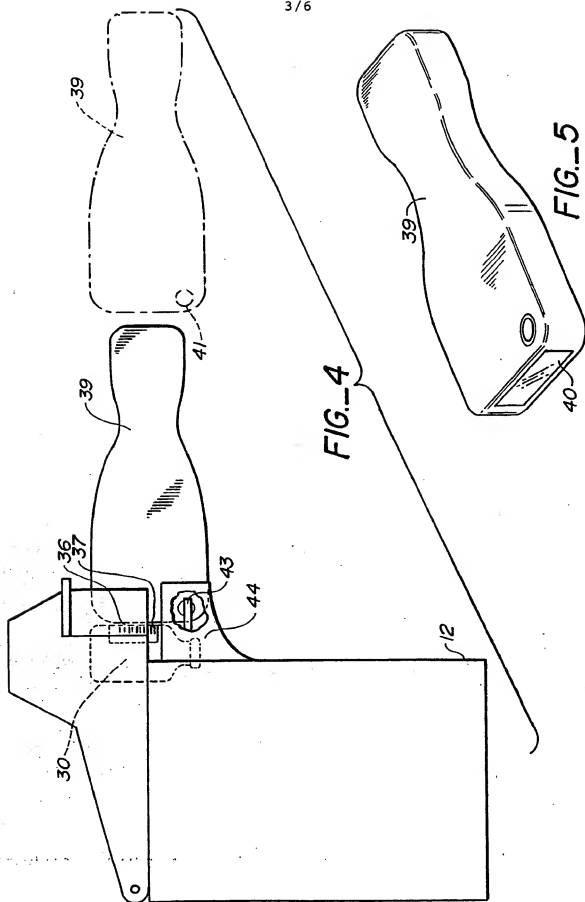


FIG.\_3



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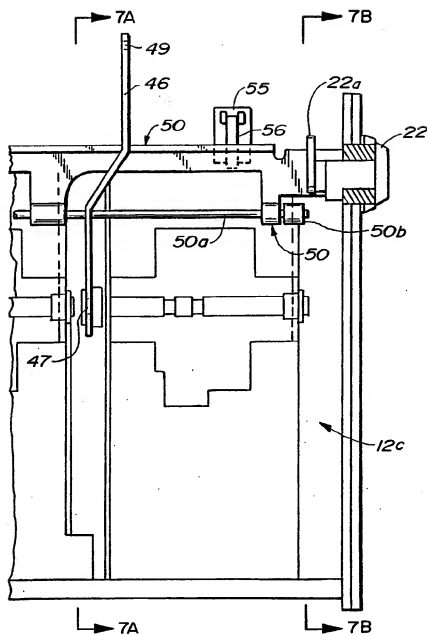
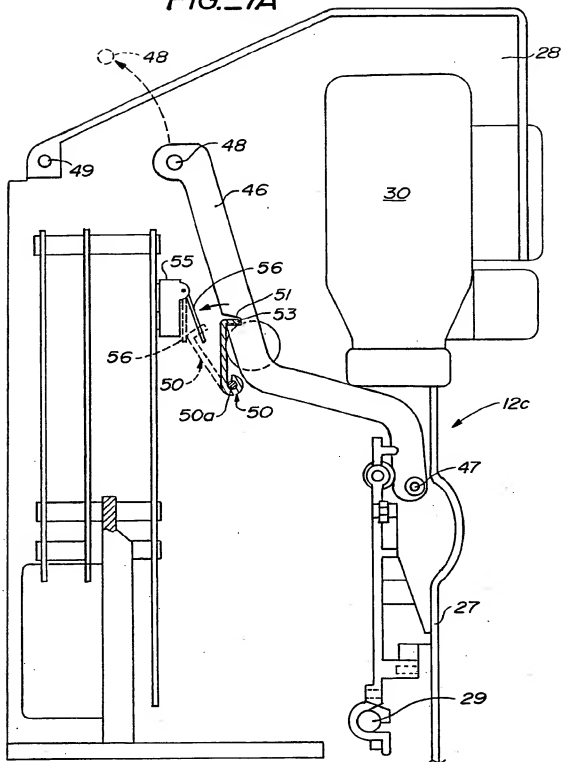
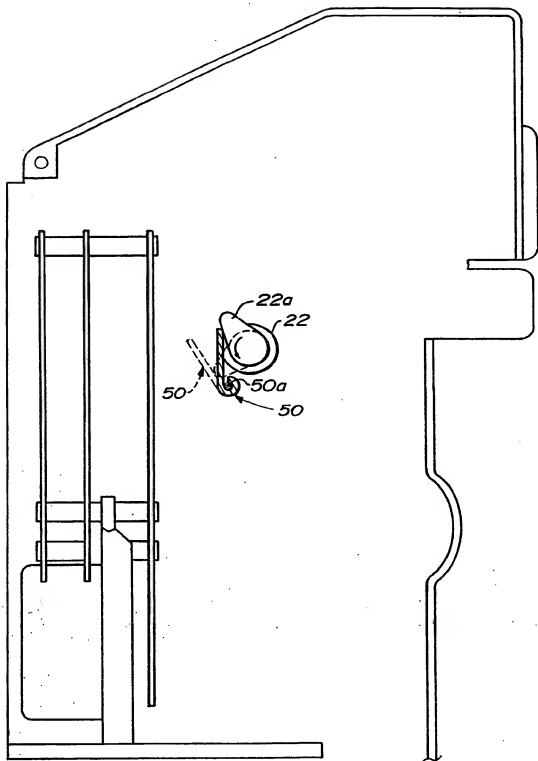


FIG. 6

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FIG. 7A

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FIG. 7B



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US92/11025

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(5) :A61M 5/00

US CL :604/131

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/151,153-155,110; 128/DIG. 12, DIG. 13

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,009,641 (GORTON) 23 April 1991, See entire document.	
A	US, A, 4,978,335 (ARTHUR, III) 18 December 1990, See entire document.	
A	US, A, 4,913,703 (PASQUALUCCI ET AL.) 03 April 1990.	
A	US, A, 4,565,542 (BERG) 21 January 1986.	
A	US, A, 4,627,839 (YOUNG) 09 December 1986.	
A,P	US, A, 5,078,683 (SANCOFF ET AL.) 07 January 1992.	

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* A document defining the general state of the art which is not considered to be part of particular relevance	* X	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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* O document referring to an oral disclosure, use, exhibition or other means		
* P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

08 MARCH 1993

Date of mailing of the international search report

06 MAY 1993

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US92/11025**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 1-14  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Please See Extra Sheet.

3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

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**BOX I. OBSERVATIONS WHERE CLAIMS WERE FOUND UNSEARCHABLE**

2. Where no meaningful search could be carried out, specifically:

The description of the device in the specification fails to allow a meaningful search under PCT Article 17(2)(a)(ii), because the specification fails to disclose the device in a sufficiently clear and concise manner as required by PCT Article 5. Specifically, the specification fails to adequately describe how the first and second interlock mechanisms are structurally configured and arranged for an operative device.